

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Medtronic, Inc., Medtronic PS
Medical, Inc., Medtronic Puerto
Rico Operations Co., and
Medtronic USA, Inc.,

Plaintiff,

v.

Brasseler USA, Inc.,

Defendant.

**MEMORANDUM OPINION
AND ORDER**

Civil No. 11-1404 (MJD/FLN)

Kurt J. Niederluecke, Lora Mitchell Friedemann and Laura L. Myers,
Fredrikson & Byron, P.A., Counsel for Plaintiffs.

Kenneth A. Liebman and Timothy M. Sullivan, Faegre & Benson LLP and
Calvin P. Griffith and David M. Maiorana, Jones Day, Counsel for Defendant.

This matter is before the Court on the motion of Plaintiffs Medtronic, Inc.,
Medtronic PS Medical, Inc., Medtronic Puerto Rico Operations Co., and
Medtronic USA, Inc. (collectively referred to herein as “Medtronic”) for
preliminary injunctive relief. By this motion, Medtronic seeks an order
temporarily enjoining Brasseler from infringing its trademark rights and the
patents-in-suit, including the manufacturing, selling or offering to sell the

accused products.

For the reasons stated herein, the motion will be denied.

I. Medtronic Products and Trademarks

The products at issue in this lawsuit comprise the Medtronic's Midas Rex® Legend® powered surgical instrument system, which consists of powered drills with interchangeable attachment and dissection tools that are designed to fit into the drills, supported by the attachments. The tools spin and are used to dissect bone, biomaterials and metal.

Medtronic asserts that the dissection tools fit in the drill using a unique, patented coupling system. The tools come in a variety of shapes and sizes, are used once and then discarded. Because of the coupling system, Medtronic asserts that only Legend® dissecting tools should be used.

The two patents at issue in this case are U.S. Patent No. 7,011,661 (the '661 patent) (Erdman Decl., Ex. 2) and U.S. Patent No. 7,066,940 (the '940 patent) (Erdman Decl., Ex. 3.) Both patents are entitled "Surgical Instrument with Rotary Cutting Member and Quick Release Coupling Arrangement." These patents include claims covering dissection tools used in surgical drills and surgical instruments using dissection tools. At issue in this motion are claim 21 of the

'940 patent and claim 34, and dependent claims 36 and 37, of the '661 patent.

Claim 21 of the '940 patent relates to "a surgical dissection tool configured for coupling with a driving member of a motor." Claim 34 of the '661 patent relates to "surgical tools for use in a surgical procedure when mated with a motor."

Each of these claims involves the unique coupling of the dissection tool with the drill.

Medtronic asserts that Defendant Brasseler USA, Inc. ("Brasseler") recently began selling imitation dissection tools for use only in the Midas Rex® Legend® system. In April 2011, Brasseler allegedly told its customers that "Our replacement burs lock into the Midas Rex® Legend® Systems the same as Midas Rex® Legend® burs." Medtronic further alleges that Brasseler's tools are inferior to Medtronic's tools and are more likely to break or perform poorly. Medtronic asserts that Brasseler's inferior products, used in its Midas Rex® drills, harms Medtronic's goodwill, as well as presents harm to patients.

In support of its motion, Medtronic has conducted tests to assess Brasseler's compatibility claims. (Hilton Decl. ¶ 17, Ex. B.) The testing included inspection of packaging, evaluation of the tool under a microscope and a performance evaluation. (Id. ¶ 18.) Medtronic asserts its testing revealed many

flaws in both packaging and performance. (Id. ¶ 19.) The testing also revealed excessive vibration, wild cutting and kicking and jumping during use. (Id.) Medtronic asserts these results indicate that Brasseler's tools may break during surgery, leaving tool fragments in the wound site. In addition to the risk to patients, Medtronic asserts that use of the Brasseler tools can compromise the performance of the Midas Rex® system.

Medtronic has also submitted evidence regarding a Brasseler imitation tool that broke in half following a surgical procedure at the Palms of Pasadena Hospital in St. Petersburg, Florida. (Foster Decl. ¶¶ 5, 9.) The broken tool jammed the drill, causing it to overheat and burn out. (Id. ¶ 9.) After learning of the breakage, Brasseler took possession of the drill, had it repaired, and the hospital has put it back into service. (Id. ¶ 11.)

Medtronic owns a number of trademarks, including the marks MEDTRONIC, MIDAS REX and LEGEND. The MEDTRONIC mark has been used since 1949, the MIDAS REX since 1965 and the LEGEND since 2002. (Galvin Decl. ¶ 5.) Each are federally registered and are incontestible under 15 U.S.C. § 1065. (Id., Exs. B-D.) Medtronic asserts that it has used its trademarks to identify the Midas Rex® system for more than a decade, and has expended substantial

time, resources and money promoting the trademarks and developing goodwill. Medtronic has spent \$44 million in marketing expenses for the Midas Rex® Legend® system, and its total revenues are approximately \$930 million; \$670 million of which is attributed to the dissection tools Brasseler is imitating.

In addition to the marks described above, Medtronic also uses a color system, product numbers and identification numbers for its products that are recognized by hospitals and surgeons. (Hilton Decl. ¶ 9.) The color system is used to identify certain attachments and the dissecting tools designed for use with such attachments. The identification number for the attachment that should be used with the dissecting tool appears in a colored bar and it is also etched on the attachment. Each attachment and tool has a separate product number used for ordering.

Medtronic alleges that Brasseler is passing off its products in two ways. First, Brasseler is falsely suggesting that the tools its sells are, in fact, Midas Rex Legend tools. For example, Brasseler's website identifies "Midas Rex Legend Burs" among the products its sells. (Galvin Decl. ¶ 12.) Brasseler sales people also state they sell Midas Rex Legend burs. (Id., Ex. F.)

Second, Brasseler omits any identifying labeling on the product presented

to operating room staff. The tool is packaged in a clear plastic tube that is then placed in an outer pouch that identifies the tool within using Medtronic's product and identification numbers and states it is for use with Midas Rex® Legend®. Once removed from the outer pouch, Brasseler's tools have no markings identifying Brasseler as the source for the product. (Hilton Decl. ¶ 23.) As a result, Medtronic asserts that Brasseler is using Medtronic's trademarks in a manner that is likely to confuse as to the relationship between the parties.

II. Brasseler Products

Brasseler asserts it has been in business for over 35 years, manufacturing and selling surgical and dental replacement tools, such as burs that fit into drills. (Miller Decl. ¶ 2.) In 1996, Brasseler began to sell replacement burs for Midas Rex Classic (I and II) and Midas Rex III. (Id. ¶ 3.) Since 2002, Brasseler has included its replacement burs for the Midas Rex Classic (I and II) and Midas Rex III in its catalogs. (Id. Exs. A-D.) Medtronic has not objected to Brasseler's use of its marks in these previous catalogs. (Id. ¶ 8.) Brasseler asserts its replacement burs for the Midas Rex® products are safe, of high quality, and comply with FDA regulations. (Jones Decl. ¶¶ 2-10; Miller Decl. ¶¶ 2-9; Lopez Decl. ¶ 24.)

In 2011, Brasseler introduced its line of replacement burs for the Midas Rex® Legend® system. In its catalog, Brasseler described these replacement burs as “High Speed Replacement Burs - • Medtronic® Midas Rex® Legend® • Stryker® TPS™ High Speed Drill.” (Galvin Decl., Ex. E.) In previous catalogs, Brasseler described its replacement tools for the Midas Rex Classic (I and II) and Midas Rex III as “Midas Rex® Replacement Instruments.” (*Id.* ¶ 5, Exs. A-D.) Since the filing of this lawsuit, Brasseler has changed its catalog, and now refers to the accused product as “Compatible with Medtronic® Midas Rex® Legend® Systems.” (Griffith Decl., Ex. C.)

Brasseler asserts that its replacement burs do not use the same design at the coupling end that is described in the patents-in-suit; that of having a bore, or hollow, cylindrical portion, at the coupling end to mate with an alignment pin. Brasseler’s burs, by contrast, have an angled, conical area at the coupling end. (Lopez Decl. ¶ 22; Conley Decl. ¶¶ 47-53.)

As of August 19, 2011, Brasseler has sold about \$330,000 of its accused replacement burs. (Minnis Decl. ¶ 2.)

III. Standard for Motion for Preliminary Injunction

To be entitled to the extraordinary relief of a preliminary injunction, the

Court must consider the following factors: 1) whether Medtronic is likely to succeed on the merits of its infringement claim; 2) whether Medtronic is likely to suffer irreparable harm if the requested injunctive relief is not granted; 3) the balance of equities; and 4) whether an injunction is in the public interest. Titan Tire Corp. v. Case New Holland, Inc., 566 F.3d 1372, 1375-76 (Fed. Cir. 2009) (citing Winter v. Natural Res. Def. Council, Inc., 555 U.S. 7, 20 (2008)). The district court has broad discretion in deciding whether preliminary injunctive relief is warranted. Id. at 1375. The burden to demonstrate that an injunction is warranted is heavier when the preliminary relief will substantially grant the relief that the movant would obtain after a trial on the merits. Rathmann Group v. Tanenbaum, 889 F. 2d 787, 790 (8th Cir. 1989).

A. Irreparable Harm

Irreparable harm exists where there is no adequate remedy at law. Modern Computer Sys., Inc. v. Modern Banking Sys., Inc., 871 F.2d 734, 737 (8th Cir. 1989). In moving for preliminary injunctive relief, failure to show irreparable harm is grounds upon which to deny the requested relief. Blue Moon Entertainment, LLC v. City of Bates City, Mo., 441 F.3d 561, 564 (8th Cir. 2006).

Courts no longer presume irreparable harm from a mere showing that a

patentee is likely to succeed on the merits of a patent infringement claim.

Instead, the Court must look at the factual record and assess this prong independently. eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 393-94 (2006).

Medtronic argues that loss of market share can constitute irreparable harm because every sale of Brasseler's imitation tools will come at its expense, since the only use of such tools is to replace Medtronic's tools. Allowing Brasseler to continue selling its imitation tools at 20-30% below Medtronic's price will erode Medtronic's market share and pricing structure.

Medtronic further argues that harm to its reputation is also irreparable. Medtronic asserts the harm to its reputation is caused by Brasseler's inferior quality imitation tools which pose a serious risk of injury to patients and to the capital equipment. Medtronic fears that when Brasseler tools perform poorly, users will blame Medtronic. The likelihood that Medtronic's reputation and goodwill will be damaged is exacerbated by the fact that the physician performing the surgery has no way of knowing that the dissection tool is a Brasseler replacement. Instead, what they see is Medtronic's prominent Midas Rex® Legend® trademarks on the drill and attachment.

Medtronic further asserts the damage is not limited to the dissection tools,

it includes injury to the Midas Rex® Legend® system as a whole, and money damages for sales of infringing dissection tools cannot remedy the damage to the reputation of Medtronic as a company and to the Midas Rex® Legend® system as a whole.

Finally, Medtronic argues that in a trademark infringement action, irreparable injury is presumed upon a showing of likelihood of confusion.

The Court finds that Medtronic cannot show that it will be irreparably harmed if injunctive relief is not granted. With respect to Medtronic's claim of trademark infringement, the Court finds that Medtronic has failed to establish a likelihood of confusion which would entitle it to a presumption of irreparable harm. See, e.g., Gen. Mills, Inc. v. Kellogg Co., 824 F.2d 622, 625 (8th Cir. 1987) (recognizing that irreparable injury can be presumed upon a showing of likelihood of confusion).

With regard to the incident at the Palms of Pasadena Hospital, it is clear that the person responsible for purchasing was fully aware that the dissecting tools purchased were Brasseler tools. (Foster Decl. ¶ 8.) Despite the fact that neurosurgery staff were unaware that the hospital had purchased Brasseler tools and were allegedly displeased with this information, it appears their displeasure

did not alter the hospital's practice of purchasing the Brasseler tools. (Id. ¶ 11.)

The record further demonstrates that Brasseler began selling replacement burs for the Midas Rex® systems in 1996, and since that time, it has been referencing the Midas Rex trademarks in its catalogs. Until now, Medtronic had never objected to Brasseler's inclusion of the Medtronic trademarks in the Brasseler catalogs, nor had Medtronic ever made a claim of unfair competition or trademark infringement. Medtronic's acquiescence to Brasseler's use of its trademarks for a number of years demonstrates that Medtronic will not be irreparably harmed if Brasseler continues to reference the Midas Rex Legend mark. See Hubbard Feeds, Inc. v. Animal Feed Supplement, Inc., 182 F.3d 598, 603 (8th Cir. 1999) (finding that delay in objecting to the use of a trademark negates a claim of irreparable injury); Tough Traveler, Ltd. v. Outbound Prods., 60 F.3d 964, 968 (2nd Cir. 1995) (same); Clam Corp. v. Innovative Outdoor Solutions, Inc., No. 08-5895 (DSD/AJB), 2008 WL 5244845, *4 (D. Minn. Dec. 15, 2008) (same).

Medtronic argues that Brasseler's most recent catalog uses the Medtronic marks in a less appropriate manner. In response to this action, however, Brasseler has changed its catalog to reference its tools as "compatible with Medtronic®MidasRex®Legend® Systems." (Griffith Decl., Ex. C.) This use is

similar to how the marks were used in Brasseler's previous catalogs. (See Miller Decl. Exs. A-D.) Accordingly, on this record, the Court finds that Medtronic has not established a likelihood of confusion.

As to Medtronic's claims of irreparable financial harm through price erosion and loss of market, the Court finds such harms are compensable by money damages. See Automated Merch. Sys., Inc. v. Crane, 357 Fed. Appx. 297 at *3 (Fed. Cir. 2009). Loss of market share must be proven to show irreparable harm; speculative claims of lost market share are not sufficient. Precision Med., Inc. v. Benstar Techs. Co., No. 10-5161, 2011 WL 1674354 at *15 (E.D. Pa. May 3, 2011). "[A] party can show irreparable harm [] if it presents evidence that the failure to grant a preliminary injunction would allow an infringer to drop its prices in order to drive the patent holder out of the market entirely." Id. (citing Automated Merch., 357 Fed. Appx. at 301).

The record thus far demonstrates that Medtronic's total revenues for the dissection tools for its Midas Rex®Legend® system is approximately \$670 million, while Brasseler's total revenues for the accused products is \$330,000. Based on this evidence, it is unlikely that Brasseler is in the position to drive Medtronic out of the dissecting tool business for its Legend® system, absent a

preliminary injunction, simply because Brasseler offers the accused products at a lower price.

The Court further finds that Medtronic's claims of loss of reputation and goodwill based on the assertions that Brasseler's products are inferior and present safety issues is speculative. The testing completed by Medtronic demonstrated that Brasseler's tools "could" result in significant injury, or "may" fracture or break, or "could" have catastrophic results. (Hilton Decl. ¶¶ 19 and 25.)

With respect to Medtronic's evidence concerning breakage, the Court notes such evidence is unclear, and in any event, insufficient to support a claim that the Brasseler tools are inferior and therefore unsafe. (See Foster Decl. ¶¶ 9-12.) Todd Foster, Medtronic's sales manager for the West Coast of Florida, stated in his declaration that he learned the Brasseler tool broke during surgery at Palms of Pasadena Hospital, jamming the drill, from the hospital's Neuro Coordinator. (Id. ¶ 9) After he traveled to the hospital and talked with the Director of Surgery, however, he learned that the tool actually broke after the surgical procedure had ended, and that there was no patient impact. (Id. ¶ 10.)

Given Brasseler's history of making and selling replacement burs for the

Midas Rex® systems, along with their FDA clearance, the record at this time does not supporting a finding that Brasseler's accused products are unsafe or will harm patients.

As Medtronic has failed to demonstrate that it will suffer irreparable harm absent a preliminary injunction, the Court need not address the remaining Dataphase factors. Accordingly, the Court finds that Medtronic is not entitled to preliminary injunctive relief.

IT IS HEREBY ORDERED that Plaintiffs' Motion for a Preliminary Injunction [Doc. No. 6] is DENIED.

Date: October 14, 2011

s/ Michael J. Davis

Michael J. Davis

Chief Judge

United States District Court

Civil No. 11-1404